

In the final Office Action, all of the claims (claims 3-16 and 23-25) were rejected as unpatentable under 35 U.S.C. Section 103 over Winston (U.S. Patent No. 4,623,536). The Office Action stated that Applicants cannot effectively distinguish the instantly claimed invention and the prior art using "only functional limitations", where the prior art has disclosed the recited components of the invention. The final Office Action further stated that Applicants' are only relying on the introduction of the relative term "flowable" that is not clearly defined, and that the prior art still discloses the recited components of the instantly claimed invention, thereby obviating the composition.

The claims of the application were also rejected as indefinite under 35 U.S.C. Section 112, second paragraph because of use of the term "flowable" and that such term is not sufficiently defined in the instant specification. The rejections are hereby traversed and reconsideration is respectfully requested.

The claims of the present application are directed to a "flowable slurry" which comprises from about 50 to 80% by weight of substantially spherical alkali metal bicarbonate particles. The particles have a median particle size of from about 0.2 to about 50.0 μm and a surface area of from about 120 to about 140 cm^3/g . These particles are disbursed in a liquid medium.

The slurry has a loose bulk density of about 1.40 to about 1.60 grams per mL as well as an Zeta potential within a set range. The slurry is stable and is prepared in the absence of a suspending agent.

The Advisory Action indicates that the term “flowable” is indefinite because the definitions provided of this term are themselves indefinite. In other words, it is the contention in the Advisory Action that the term “flowable” must be defined in terms of how much of a change of place constituent particles of a slurry move and whether this occurs in seconds, minutes or hours. Furthermore, the Office Action contends that this change of place does not take place on its own but rather is the result of an applied force which is not defined. Thus, the Office Action takes the position that the term “flowable” is indefinite. As Applicants have shown, flowability is an inherent property of the term “slurry” and therefore, the Office Action alleges that the term “slurry” is likewise indefinite. Accordingly, the claims are rejected as indefinite such that one of ordinary skill in the art could not possibly know what the claim means in the context of the present invention. Applicants’ strongly disagree.

It is well established that the words of the claim are given their ordinary and customary meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 39 USPQ 2d 1573 (Fed. Cir. 1996), reaffirmed in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

The ordinary and customary meaning of a term is the meaning that the term would have to the person of ordinary skill in the art at the time of the invention. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Thus, one has to look at the person of ordinary skill in the art at the time of the invention as the person whom the ordinary and customary meaning of a term as used in a patent application is addressed. To facilitate the person of ordinary skill in the art in understanding the claim term, he or she is deemed to read the claim term, not only in the context of the particular claim in which the term appears, but in the context of the entire patent including the specification. Phillips supra. Thus, the meaning of the term “slurry” (as well as the meaning of the term flowable) as they appear in the present claims must be ascertained from the reading of the claim as well as a reading of the specification and it must also be determined whether the inventor has used any of these terms in a manner inconsistent with their ordinary meaning. Vitronics Corp. supra.

Referring to the specification, beginning with the bottom portion of page 1, there is a discussion of the state of the art and the acknowledgement that coarse grain alkali metal bicarbonate particles of the prior art are often combined with a liquid medium to form slurries. Accordingly, Applicants’ acknowledge the prior art was well aware of the term “slurry” and the meaning of the term was known to those of ordinary skill in the art.

The difficulty with prior art slurries is discussed beginning at the top of page 2 of the specification. In particular, the alkali metal bicarbonate particles separate from the liquid medium after only a few minutes. Suspension aides are required to overcome this problem. Suspension aides, however, are disadvantageous for several reasons and are specifically omitted from the present claims.

Another disadvantage of the prior art slurries is that when they are further diluted with water, the amount of alkali metal bicarbonate particles dissolved in the liquid medium decreases as the temperature is reduced. Page 2, beginning at line 14, indicates that time and fuel must be used to increase the temperature of the slurry in order to facilitate the dissolution of the sodium bicarbonate particles. When such dilutions are used as "dialyzates", both the cost and time of the medical treatment is increased. Thus, the slurry of the present invention can be used as a dialyzate, another term that is well known to those of ordinary skill in the art. Applicants' enclose herewith a definition of "dialyzate" taken from a recognized technical dictionary (Dorland's Illustrated Medical Dictionary 26th Edition) in which the term is defined as "the material that passes through the membrane in dialysis." The term "dialysis" is defined as the process of separating crystalloids and colloids in solution by the difference of the rates of diffusion through a semi-permeable membrane. In other words, the crystalloids as well as the liquid medium containing the same pass through the membrane while colloids are impeded or do not pass through the membrane at all.

Accordingly, the term “dialyzate” clearly refers to a liquid containing suspended solid material that “flows” through a dialysis membrane. This is an example of the slurry that is given in the specification. One of ordinary skill in the art reading the example of a slurry given in the specification would readily conclude that the slurries claimed and described in the specification are flowable as that term is customarily ordinarily used in the art of the present invention.

The dictionary definitions of the term “slurry” that have been provided previously all concur with this understanding of those skilled in the art. Accordingly, intrinsic evidence (the specification) and extrinsic evidence (dictionary definitions) all of record in the present application are in agreement. The word “slurry” must be given its ordinary and customary meaning, that meaning is well known to those of ordinary skill in the art, and a skilled artisan would have no difficulty understanding the meaning of this term within the context of the present claims.

However, support for the well known understanding the term “slurry” does not end with the analysis. As previously indicated, the claims require that the slurry have a loose bulk density of 1.40 to 1.60 grams per ml. Loose Bulk Density is therefore a limitation of the present claims and helps define the nature of the slurry. The term “loose bulk density” is based on the amount of material (measured in grams) per unit volume of liquid medium (mL). The greater the loose bulk density the more solid material is present in the liquid medium. If the loose bulk density is increased, there

will reach a point where the composition is no longer a slurry but rather a non-flowable composition. Therefore, the claimed range for the loose bulk density, the extensive information provided in the specification including exemplification of a dialyzate formulation, and dictionary definitions previously provided which are consistent with the specification, all support the conclusion that the term "slurry" was well known to those of ordinary skill in the art.

Applicants therefore submit that the claims of the present application are definite insofar as the term "slurry" is employed and that the term "flowable" is an inherent part of the term "slurry" and is likewise definite.

In further support of the proposition that the term "slurry" and the specific term "flowable slurry" are accepted terms in the art, Applicants refer to prior art references cited in the present application which employ the term "slurry" in the absence of a specific quantified definition thereof. More specifically, Vanzo (U.S. Patent No. 5,075,432) shows the preparation of slurries in comparative Example 1 appearing in column 3 and in the working examples beginning with Example 1 in column 4. In each case, there is produced a "slurry" of cyclodextrin without any definition of the term "slurry" presented anywhere in the specification.

Itob (U.S. Patent No. 5,071,558) is relevant to this issue in two important respects. First, it is a patent directed to the preparation of an electrolyte granule A composed mainly of sodium chloride and an electrolyte granule B containing sodium

bicarbonate. As indicated at column 6, beginning at line 16, granule B (containing sodium bicarbonate) is put into water and stirred under a magnetic stirrer, until the sodium bicarbonate dissolved. As indicated at column 6, lines 24-25 the granule B was found to have excellent "flowability", a term which is not otherwise defined in the patent reference. Second, there is specific reference to usefulness of such compositions for the preparation of dialyzates which likewise must be flowable as previously discussed.

Masters (U.S. Patent No. 5,855,871) discloses a two component dentifrice composition. As shown in Example 3, a mixture is made of a bicarbonate component with other ingredients. The mixture is then diluted with water to form a "slurry" (column 10, lines 33-37). Waggener (U.S. Patent No. 3,780,160) utilizes the term "slurry" in claim 1 which is directed to a process for the production of sodium bicarbonate.

All of these references used the term "slurry" and/or "flowable" long before the effective date of the present application. The use of such terms within the content of patent documents is further significant evidence of the customary and ordinary meaning of these terms and that the person of ordinary skill in the art was fully familiar with such terms and their meaning.

Applicants therefore submit that the rejection of the present claims under 35 U.S.C. Section 112 because of use of the term "flowable" and "slurry" is unsupported based on the evidence in this case and should be withdrawn.

Applicants acknowledge that the Office Action takes the position that the term "slurry" is indefinite and therefore is broad enough to include "toothpaste" which is the subject matter of the sole prior art reference currently relied on to reject the present claims (Winston). However, it should be noted that the Assignee herein has received a Notice of Allowance in a pending application for related subject matter (U.S. Patent Application Serial No. 10/116,766) in which the preamble of the allowed claimed subject matter is "A Storage Stable Prepackaged Flowable Slurry" comprising among other ingredients, sodium bicarbonate. Thus, in a related case, the same phrase "flowable slurry" was employed and accepted as meeting the requirements of 35 U.S.C. Section 112. In addition, during prosecution of that application, a reference (Eichel, U.S. Patent No. 4,024,237) was cited. This reference is directed to compositions for establishing environmental conditions favorable to oral leucocytes. This reference teaches four groups of different reagents which promote leucocyte function. Sodium bicarbonate is mentioned as an example of one group of reagents.

The reference patent contains eight claims. Claims 1-6 are directed to a composition for establishing environmental conditions in the human oral cavity for

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maintaining healthy functional oral leucocytes. Claim 7 is directed to a process which comprises applying orally a composition as defined in claim 1. Of particular importance to the issues herein is claim 8 which reads as follows:

“8. A process as defined in claim 7 wherein said composition is applied as a solution, slurry, powder or as a toothpaste.”

This claim clearly shows that there is an art recognized difference between the term “slurry” and “toothpaste”. Applicants have previously advised that toothpaste compositions do not flow and are not in the form of a slurry. U.S. Patent No. 4,024,237 clearly recognizes this distinction by listing slurry and toothpaste as separate and distinct components. In addition, as previously explained, a dialyzate is flowable and therefore cannot function in the form of a toothpaste. Accordingly, the Winston toothpaste formulations are not a teaching or suggestion of a slurry as that term is employed in the present invention.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

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It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Allen R. Kipnes", written over the printed name and registration information.

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Medical Dictionary

Twenty-sixth Edition

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tion of the exact level of a lesion; as, for instance, of an intervertebral tumor. **pathologic d.**, diagnosis by observing the structural lesions present. **physical d.**, determination of disease by inspection, palpation, percussion, and auscultation. **provocative d.**, the induction of a condition for the purpose of diagnosis, as the induction of a fit in a doubtful case of epilepsy. **roentgen d.**, diagnosis made by means of roentgen rays. **serum d.**, diagnosis by means of the analysis of serums; immuno-diagnosis.

diagnostic (di'ag-nos'tik) pertaining to or subserving diagnosis; distinctive of or serving as a criterion of a disease, as signs and symptoms.

diagnosticate (di'ag-nos'te-kät) diagnose.

diagnostician (di'ag-nos'tish'an) an expert in diagnosis.

diagnostics (di'ag-nos'tiks) the science and practice of diagnosis of disease.

diagnosticum (di'ag-nos'te-kum) a preparation used in tests and experiments. **Ficker's d.**, an emulsion of killed typhoid bacilli for use in the Gruber reaction.

diagram (di'ah-gram) a graphic representation, in simplest form, of an object or concept, made up of lines and lacking entirely any pictorial elements. **vector d.**, a diagram representing the direction and magnitude of electromotive forces of the heart for one entire cycle, based on analysis of the scalar electrocardiogram. **diagrammatic** (di'ah-grah-mat'ik) pertaining to or of the nature of a diagram.

diagraph (di'ah-graf) [dia- + Gr. *graphein* to write] an instrument for recording outlines; used in craniometry, etc.

diakinesis (di'ah-ki-ne'sis) [dia- + Gr. *kinesis* motion] the stage of first meiotic prophase in which the nucleolus and nuclear envelope disappear and the spindle fibers form.

Dial (di'al) trademark for a preparation of allobarbitol.

dial (di'al) [L. *dialis* daily, from *dies* day] a circular area with graduations around the circumference and a centrally fixed pointer for indicating values of time, pressure, etc. **astigmatic d.**, a diagram arranged like the face of a watch used to determine the presence and axis of astigmatism.

Dialister (di'ah-lis'ter) a genus of minute gram-negative rod-shaped bacteria found in the respiratory tract. They pass some bacteria-proof filters, and at one time *D. pneumonies* was thought to be etiologically related to epidemic influenza.

diallyl (di'al'il) 1. any compound containing two allyl molecules. 2. a liquid unsaturated hydrocarbon, $\text{CH}_2=\text{CH}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2$, having the odor of radishes. **d.** sulfide, allyl sulfide.

diallylbisnortoxiferin dichloride (di'al'il-bis-nor-tok'si-fer-in) alcuronium chloride.

Dialog (di'ah-log) trademark for a preparation of allobarbitol and acetaminophen.

Dialume (di'ah-loom) trademark for a preparation of dried aluminum hydroxide gel.

dialurate (di'al'u-rät) a salt of dialuric acid.

dialysance (di'ah-li'sans) [dialysis + -ance suffix denoting action or process] the minute rate of net exchange of a substance between blood and bath fluid, per unit blood-bath concentration gradient; a parameter in artificial kidney kinetics (nonfiltration) functionally equivalent to the clearance of the natural kidney.

dialysate (di'al'i-sät) the material that passes through the membrane in dialysis.

dialysis (di'al'i-sis) [dia- + Gr. *lysis* dissolution] the process of separating crystalloids and colloids in solution by the difference in their rates of diffusion through a semipermeable membrane: crystalloids pass through readily, colloids very slowly or not at all. See also *hemodialysis*. **Abderhalden's d.**, Abderhalden's reaction. **cross d.**, dialytic parabiosis. **equilibrium d.**, a technique employed to measure primary interaction of hapten and antibody. A container is employed in which two cells are separated by cellophane. Antibody is placed in one cell and hapten in the opposite one. The hapten will pass through the cellophane until, at equilibrium, an equivalent number of free hapten molecules is present in either cell on opposite sides of the membrane. In the cell containing antibody, additional hapten is present, combined with the antibody molecules. The use of radiolabeled hapten molecules permits calculation of the ratio of bound to free hapten, thus permitting determination of the association constant of hapten antibody reactions. **lymph d.**, removal of urea and other elements from lymph collected from the thoracic duct, treated outside the body, and later reinfused. **peritoneal d.**, dialysis through the peritoneum, the dialyzing solution being introduced into and removed from the peritoneal cavity as either a continuous or an intermittent procedure. **d. ret'inae**, a tear in the retina at the ora serrata.

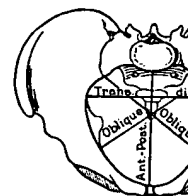
dialyzable (di-ah-liz'ah-b'l) capable of dialysis or of passing through a membrane.

dialyzed (di'ah-lizd) separated or prepared by dialysis.

dialyzer (di'ah-liz'er) an apparatus for effecting dialysis; see *hemodialyzer*.

Diamanus (di'ah-ma'nus) a genus of fleas. *D. montanus*, a flea of rodents in the western United States which has been implicated in the transmission of sylvatic plague; formerly called *Ceratophyllus acutus*, *C. montanus*, and *Oropella montana*.

diameter (di-am'e-ter) the length of a straight line passing through the center of a circle and connecting opposite points on its circumference; hence the distance between two specified opposite points on the periphery of a structure such as the cranium or pelvis. **anteroposterior d.**, the distance between two points located on the anterior and posterior aspects, respectively, of the structure being measured; such as the true conjugate diameter of the pelvis, or the occipitofrontal diameter of the skull. **anterotransverse d.**, of the cranium; temporal d. **Baudelocque's d.**, external conjugate diameter. **bischial d.**, transverse diameter of pelvic outlet. **biparietal d.**, the distance between the two parietal eminences. **bisacromial d.**, the distance between the outermost points of the shoulder. **bischial d.**, the distance between the two most remote points of the iliac crests. **bispinous d.**, the distance between the opposite spines of the ischia. **bitemporal d.**, the distance between the two extremities of the coronal suture. **buccolingual d.**, the distance from the buccal to the lingual surface of a tooth crown at its widest point or greatest curvature. **cervicobregmatic d.**, the distance between the center of the anterior fontanel and the junction of the neck with the floor of the mouth. **coccygeopubic d.**, the distance from the tip of the coccyx to the under margin of the symphysis pubis. **conjugate d.**, the distance between two specified opposite points on the periphery of the pelvic inlet, usually used in reference to the true conjugate diameter. **conjugate d., anatomic**, the true conjugate diameter. **conjugate d., diagonal**, a diameter of the pelvic inlet; the distance from the posterior surface of the pubis to the tip of the sacral promontory; called also *conjugata diagonalis* and *diagonal conjugate*. **conjugate d., external**, the distance from the depression under the last lumbar spine to the upper margin of the pubis; called also *external conjugate* and *Baudelocque's d. or line*. **conjugate d., internal**, true conjugate d. **conjugate d., obstetric**, the shortest anteroposterior diameter of the pelvic inlet; the distance from a point 1 cm. below the top of the pubis to the tip of the sacral promontory, measuring 11 to 13 cm. in the normal pelvis. So called because it is intimately concerned in the process of labor. Called also *obstetric conjugate* and *conjugata vera obstetrica*. **conjugate d., true**, the anteroposterior diameter of the superior aperture of the minor pelvis (pelvic inlet), measured from the superior margin of the symphysis pubis to the sacrovertebral angle; called also *conjugata* [NA], *conjugata anatomica*, *conjugata vera*, *anatomic*, *internal*, or *true conjugate*, and *anatomic conjugate d.* **cranial d's**, distances measured between certain landmarks of the skull, such as the *biparietal d.*, *bitemporal d.*, *cervicobregmatic d.*, *frontomental d.*, *occipitofrontal d.*, *occipitotemporal d.*, and *suboccipitobregmatic d.* **craniometric d.**, any line connecting two craniometric points of the same name. **extracanthic d.**, the distance between the lateral points of junction of the upper and lower eyelids of the two eyes. **frontomental d.**, the distance from the forehead to the chin. **fronto-occipital d.**, occipitofrontal d. **intercanthic d.**, the distance between the medial points of junction of the upper and lower eyelids of the two eyes. **intercrystal d.**, the distance between the middle points of the iliac crests. **intertuberal d.**, the distance between the sciatic notches. **longitudinal d., inferior**, the distance from the foramen cecum to the internal occipital protuberance. **mento-occipital d.**, occipitotemporal d. **mentoparietal d.**, the distance from the chin to the vertex of the skull. **d. obli'qua pel'vis** [NA], oblique diameter of pelvis, the oblique diameter of the superior aperture of the iliopectineal eminence of the other side. Designated right or left depending on the sacroiliac joint used for reference; the left is uniformly 0.5 cm. shorter than the right. **occipitofrontal d.**, the distance from the external occipital protuberance to the most prominent midpoint of the frontal bone; called also *fronto-occipital d.* **occipitotemporal d.**, the distance from the external occipital protuberance to the most prominent midpoint of the chin; called also *mento-occipital d.* **parietal d.**, the distance between tuberosities of parietal bones; called also *posterior transverse d.* **pelvic d.**, any diameter of the pelvis. **posterior transverse d.**, parietal d. **pubosacral d.**, true conjugate d. **pubotuberosus d.**, the distance from the tuberosity of the ischium to a point on the superior ramus of the pubis which is located directly perpendicular to the tuberosity. **sacropubic d.**, the distance from the tip of the sacrum or coccyx to the lower margin of the symphysis pubis. **sagittal d.**, the distance from the glabella to the external occipital protuberance. **suboccipitobregmatic d.**, the distance from the lowest posterior point of the occiput to the center of the anterior fontanel. **temporal d.**, the distance between the tips of the alae magne; called also *anterotransverse d.* **d. transversa pel'vis** [NA], transverse diameter of pelvis; the greatest distance from side to side of the superior aperture of the minor pelvis. **transverse d.**, the distance between two points located on the opposite sides of the body part being measured, such as the biparietal diameter of the head. **transverse d. of pelvis**, d. transversa pelvis. **transverse**



Diameters of pelvic inlet (see also p. 371)

d. of pelvic outlet, the distance of the ischial tuberosities (average). **bischial d.**, **vertebromammillary** diameter of the chest. **vertical d.**, points situated on the upper and lower being measured, such as the distal foramen and the vertex of the skull.

diamide (di-am'id) [L. di two + an contains two amide groups. 2. hydriamidine (di-am't-dén) a compound groups.

diamido- a prefix indicating the groups.

diamine (di'ah-mén'; di'ah-mín') [L. pound which contains two amino groups, $\text{N}_2\text{H}_5\text{HSO}_4$, used as a germicide. **d.**

diaminoacridine (di-am't-no-ak'r'i-diaminodiphenylsulfone (di-am'none. **diacetyl d.**, acetadone.

diaminodiphosphatide (di-am'ti-phatide containing two atoms of niti to the molecule.

diaminomonophosphatide (di-a-phosphatide containing two atoms phosphorus to the molecule.

diaminuria (di-am't-nu're-ah) the urine.

diamniotic (di'am-ne-ot'ik) having rate amniotic cavities, as diamniotic

diamocaine cyclamate (di-ah'mv (2-anilinoethyl)-4-(2-diethylamino)ethyl local anesthetic, $\text{C}_{17}\text{H}_{23}\text{N}_3\text{O}_5\text{S}$.

diamonds (di'ah-munz) an uterine characterized by well-defined quadra the skin.

diamorphine (di'ah-mor'fén) diac

diamorphosis (di'ah-mor-to'sis) shape.

Diamox (di'ah-moks) trademark f amide.

diamthazole dihydrochloride name: 6-(2-diethylaminoethoxy)-2-dihydrochloride. An antifungal agent against species of *Trichophyton* and *Albicans*; it has been used in the treatment, applied topically.

diamylene (di-am't-lén) dipentene

Diana complex (di-an'ah) [in Rome the moon, hunting, and chastity] s

Dianabol (di-an'ah-bol) trademark

diandry (di-an'dre) [di-(1) + Gr. *an* which the extra haploid set is of pa

dianhydroantigenin (di'an-hi aglycone, $\text{C}_{22}\text{H}_{34}\text{O}_6$, from antiarin.

dianoetic (di'ah-no-et'ik) [dia- + G the intellectual functions, especially

dianthebrachia (di'an-te-bra'ke-ah) characterized by duplication of a fo

diamide (di-ap'ah-mid) chemist 3-methylsulfonylbenzamide; a di $\text{C}_6\text{H}_5\text{CONH}_2\text{O}_2\text{S}$.

Diaparene (di-ap'ah-rén) tradema ybenzenethionium chloride.

diapause (di'ah-pawz) [dia- + Gr. *pa* tivity and arrested development; i

creased metabolism, as in many s seeds; it is a mechanism for survivi

diapedesis (di'ah-pé-de'sis) [dia- + ward passage through intact vessel of the blood; called also *diaporesis* a